MAR 1 8 2005

K04/311

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: TIGER MEDICAL PRODUCTS LTD
2-Address: **Liu Lin Tower, Suite 1910. 1 Huai Hai Zhong Road. Shanghai 200021 CHINA**
3-Phone: +86-21-6386-6300
4-Fax: +86-21-5383-5200
5-Contact Person: Mark Engel, President
6-Date summary prepared: April 15th, 2004
7- Official Correspondent: TIGER REGULATORY
8- Address: 1308 Morningside Park Dr. Alpharetta, GA 30022 USA
9- Phone: (770) 777-4146
10- Fax (678) 623- 3765
11- Contact person: Jay Mansour
12-Device Trade or Proprietary Name: Tiger Endotracheal tubes (various models and sizes)
13-Device Common or usual name: Tracheal tubes
14-Device Classification Name: Tracheal tubes
15-Substantial Equivalency is claimed against the following device:

- For oral/nasal, cuffed and uncuffed: K892432
- For nasal only, cuffed: K931164
- For oral only, cuffed: K931163
- For nasal only, uncuffed: K931165
- For oral only, uncuffed: K931166

11-Description of the Device:

Tiger Medical Products Ltd's Endotracheal tube is available in 90 different variants distributed among 6 main configurations and different sizes, as detailed below. It is marketed as sterile, single use, for airway management.
It consists of a clear tracheal tube with radiopaque blue stripe running its entire length, and it is graduated with multiple centimeter markings to allow easy detemination of intubated length, and is terminated with a 15mm standard connector.
It conforms to ISO 5261: 1999 and ASTM F1242: 1996 with one minor exception in the tube marking.

The six categories (or configurations) are listed below:

(a) CATEGORY 1: uncuffed, oral/nasal:
It is provided as uncuffed, murphy, oral/nasal, and in 0.5mm ID increments from sizes 2.0 to 10.0 inclusive, totalling 17 sizes

(b) CATEGORY 2: uncuffed, nasal only:
It is provided as uncuffed, murphy, preformed nasal- 2 eyes, and in 0.5mm ID increments from sizes 2.0 to 10.0 inclusive, totalling 17 sizes

(c) CATEGORY 3: uncuffed, oral only:
It is provided as uncuffed, murphy, preformed oral- 2 eyes, and in 0.5mm ID increments from sizes 2.0 to 10.0 inclusive, totalling 17 sizes

(d) CATEGORY 4: cuffed, oral/nasal:
It is provided as cuffed, murphy, oral/nasal, and in 0.5mm ID increments from sizes 4.0 to 10.0 inclusive, totalling 13 sizes

(e) CATEGORY 5: cuffed, nasal only:
It is provided as cuffed, murphy, preformed nasal, and in 0.5mm ID increments from sizes 4.0 to 10.0 inclusive, totalling 13 sizes

(f) CATEGORY 6: cuffed, oral only:
It is provided as cuffed, murphy, preformed oral, and in 0.5mm ID increments from sizes 4.0 to 10.0 inclusive, totalling 13 sizes

12-Intended use of the device: (refer to FDA form attached)

The intended use for all the product variants is grouped into three different sections:

(a) CATEGORY 1 (uncuffed, oral/nasal) and CATEGORY 4 (cuffed, oral /nasal):
The intended use of this device is to be intubated into a patient's trachea via the nose or mouth for airway management.

(b) CATEGORY 2 (uncuffed, nasal only) and CATEGORY 5 (cuffed, nasal only):
The intended use of this device is to be intubated into a patient's trachea via the nose for airway management, specifically for use in surgical procedures involving the head, neck and face.

(c) CATEGORY 3 (uncuffed, oral only) and CATEGORY 6 (cuffed, oral only):
The intended use of this device is to be intubated into a patient's trachea via the mouth for airway management, specifically for use in surgical procedures involving the head, neck and face.

13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device. Refer to the explanations/details within the main submission.

FDA file reference number:	510k #
Uncuffed, oral/Nasal	K892432
Uncuffed, nasal only	K931165
Uncuffed, oral only	K931166
Cuffed, oral/Nasal	K892432
Cuffed, nasal only	K931164
Cuffed, oral only	K931163
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Similar
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	N/A
Compatibility with environment and other devices	N/A
Where used	Identical
Standards met	Similar
Electrical safety	N/A
Thermal safety	N/A
Radiation safety	N/A

Refer to the submission for more details concerning dimensional and technological comparisons for all 6 categories, as well as corresponding engineering drawings and samples supplied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2005

Tiger Medical Products, Limited
C/O Mr. Jay Mansour
Tiger Regulatory
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K041311
Trade/Device Name: Tiger Endotracheal Tubes
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: February 28, 2005
Received: March 4, 2005

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

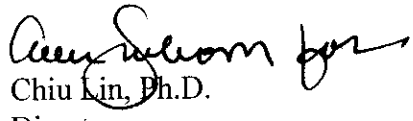
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Tiger Endotracheal Tubes

Indications For Use:

The indication for use for all the product variants is grouped into three different sections:

(a) Uncuffed, oral/nasal and Cuffed, oral /nasal:
The intended use of this device is to be intubated into a patient's trachea via the nose or mouth for airway management.

(b) Uncuffed, nasal only and Cuffed, nasal only:
The intended use of this device is to be intubated into a patient's trachea via the nose for airway management, specifically for use in surgical procedures involving the head, neck and face.

(c) Uncuffed, oral only and Cuffed, oral only:
The intended use of this device is to be intubated into a patient's trachea via the mouth for airway management, specifically for use in surgical procedures involving the head, neck and face.

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K041311

Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K041311